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E.O. 12958: N/A

TAGS: ECON ETRD EINV KIPR ES  
SUBJECT: EL SALVADOR APPROVES DATA EXCLUSIVITY REGULATIONS

SENSITIVE BUT UNCLASSIFIED; HANDLE ACCORDINGLY

¶1. (SBU) SUMMARY. El Salvador has passed long-awaited regulations on data protection and data exclusivity, one of their last major outstanding CAFTA-DR commitments. According to a leading intellectual property lawyer, the regulations were an important step forward for intellectual property, finally offering legal recourse to protect clinical data. On the other hand, the domestic pharmaceutical industry opposed the regulations as published. Given the pharmaceutical industry's political power, implementation of the regulations may be limited. END SUMMARY.

¶2. (SBU) Shortly before El Salvador's annual August holidays, the Government of El Salvador published new regulations for data protection and data exclusivity for pharmaceutical products. At the same time, El Salvador also acceded to the "Convention Related to the Distribution of Programme-Carrying Signals Transmitted by Satellite (1974)," also known as the Brussels Convention.

¶3. (SBU) Danilo Rodriguez, a lawyer and head of the Salvadoran Intellectual Property Association, told Econoff that the regulations were "good enough to promote them to clients" and finally offered legal recourse for firms whose data was used to produce "knock-off" drugs. For them to be truly effective, however, the Public Health Council would need to change its rules on product registration to catch compliance issues early in the process, rather than waiting for a complaint to be brought in court.

¶4. (SBU) Jose Mario Ancalmo, head of the domestic pharmaceutical industry organization INQUIFAR, offered a less favorable view. In Ancalmo's view, the Government had "completely ignored" the domestic industry's input, and the regulations were an illegitimate way to "extend expired patents." According to Ancalmo, the domestic industry lacks the infrastructure to obtain the clinical data for a new product, so he would expect fewer new releases.

¶5. (SBU) COMMENT: The passage of the regulations marks the last of El Salvador's major intellectual property commitments under CAFTA-DR. The fact that El Salvador's politically powerful domestic pharmaceutical industry, which opposes any new intellectual property regulations, was upset by the regulations suggests that the regulations do what they need to do. The domestic industry's opposition, however, may hinder effective implementation of the regulations by the Public Health Council.

Glazer